Proof-of-Concept Process: Web Access to Research Protocols On-Line

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Background. Immediate access to protocol information, including eligibility criteria and drug dosing schedules is critical to clinical and research staff at the City of Hope (COH) National Medical Center. Early in 1996, COH began a project aimed at providing authorized staff access to over 150 research protocols via the COH intranet with a goal of avoiding potentially dangerous drug dosing errors and eliminating the inefficient and difficult to maintain paper system. Before developing a production version of Research Protocols On-Line, project management decided to use a proof-of-concept process which included the development and piloting of a prototype and pre- and post-evaluations.

Methodology. An interdisciplinary task force defined a prototype modeled after the current paper system with enhancements that capitalized on features of Web technology. A group of approximately fifty pilot users was identified to be trained and to use the prototype for a three-month pilot period. The goal of the pilot was to assess technological alternatives, validate the design of the system and test the evaluation instruments.

Eight active protocols were selected for inclusion in the pilot. Acrobat Reader was selected to display all existing documents currently maintained in a word processing format. The task force decided to constrain the content of the Web pages to data already maintained in a Biostatistics protocol tracking database to ensure that the full system could be implemented quickly with existing data. It was recognized early in the design of the pilot that the project would need to include a migration of the Biostatistics database to a Web-accessible database product (MS SQL Server was selected) to allow greater flexibility in delivering protocol information; for the pilot, however, all HTML files were hand-coded.

The pilot system includes a main menu page, three different access techniques, a list of protocol contact personnel, a list of known problems and a mechanism for reporting problems. It can be used to access individual synopses, full protocols, pharmacy summaries and informed consents, and to send e-mail messages to protocol contact personnel. An e-mail link was provided on all pages for submitting suggestions.

Pre-pilot evaluations were administered which were designed to assess user satisfaction with the attributes of the current paper system: currency of information, ease of locating information, completeness and readability. Post-evaluation surveys assessed the extent of use of the system and satisfaction with the components of the prototype and with look-and-feel attributes.

Results. The pilot clarified issues with the technological alternatives. Users were very satisfied with the Acrobat Reader features; from a maintenance point of view, however, alternative methods of authoring *new* protocols directly in a Web-deliverable format will be assessed for future use. Additionally, the decision to convert to MS SQL Server was confirmed in that users desired to have more flexibility in querying the system. Greater than 75% of the ratings were very or extremely satisfied for all system attributes evaluated. However, users did provide suggestions which will be incorporated in the initial production version, including the following: add provisions for e-mail links to a broader range of personnel, increase font sizes, eliminate secondary-level accesscode, and provide more searchability features. Other requests, such as linking protocols to a list of patients on protocol will be deferred.

Conclusion. Besides clarifying product design, the prototype has allowed a more realistic project schedule to be developed. The existence of the prototype also provided impetus for looking more closely at the cultural and administrative changes required to support the project. During the pilot, business priorities changed and higher priority was given to implementing an Internet version in order to increase patient enrollment. The prototype approach and the choice of the Web for implementing the intranet version made us well-poised for adapting to the shift in priorities.

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